Attachment C2

JUN 27 2011

K101509

510 (k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
Address	3F, 5F, No. 127, Wugong 2nd Rd., Wugu Township, Taipei County, 24888, Taiwan
Phone	(+886-2) 6625-8188 ext.1176
FAX	(+886-2) 6625-0288
E-mail	teling.hsu@taidoc.com.tw
Date Prepared	May 31st, 2010

2. Name of Device

Trade/Proprietary Name	U-RIGHT TD-4279A Blood Glucose Monitoring System, U-RIGHT TD-4279B Blood Glucose Monitoring System, U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System, U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System, FORA GD40a/TD-4272A Blood Glucose Monitoring System, FORA GD40b/TD-4272B Blood Glucose Monitoring System, FORA Wisdom GD40a/TD-4272A Blood Glucose Monitoring System and FORA Wisdom GD40b/TD-4272B Blood Glucose Monitoring System
Common Names	Blood glucose test system
Product Code	NBW, LFR
Classification Panel	Clinical Chemistry (75)
Regulations	Class II 21 CFR 862.1345

3. Predicate Device

Trade/Proprietary Name:	FORA G31 Blood Glucose Monitoring System (Model TD-4256)
Common/Usual Name:	Blood glucose test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K094005

4. Device Description

The U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b Blood Glucose Monitoring Systems consist of three main products: the meter, test strips and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only U-RIGHT TD-4279 A/B test strips and FORA GD40a/b test strips for the U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b Blood Glucose Monitoring Systems, and use with FORA control solutions to perform quality checks.

The blood glucose detection method and measurement is by an electrochemical biosensor technology using FAD-dependent glucose dehydrogenase (FAD-GDH).

5. Intended Use

For single use

U-RIGHT TD-4279A Blood Glucose Monitoring System

The U-Right TD-4279A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279A Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The U-Right TD-4279 A Test Strips are for use with the U-Right TD-4279A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

U-RIGHT TD-4279B Blood Glucose Monitoring System

The U-Right TD-4279B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279B Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The U-Right TD-4279B Test Strips are for use with the U-Right TD-4279B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

FORA GD40a/TD-4272A Blood Glucose Monitoring System

The FORA GD40a /TD-4272A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40a / TD-4272A Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The FORA GD40a /TD-4272A Test Strips are for use with the FORA GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

FORA GD40b/TD-4272B Blood Glucose Monitoring System

The FORA GD40b / TD-4272B Blood Glucose Monitoring System is intended to be used

for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40b / TD-4272B Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The FORA GD40b / TD-4272B Test Strips are for use with the FORA GD40b / TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

For multiple patient use

U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System

The U-Right TD-4279A MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279A MULTI Test Strips are for use with the U-Right TD-4279A MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System

The U-Right TD-4279B MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with

single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279B MULTI Test Strips are for use with the U-Right TD-4279B MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

FORA Wisdom GD40a/TD-4272A Blood Glucose Monitoring System

The FORA Wisdom GD40a /TD-4272A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40a / TD-4272A Test Strips are for use with the FORA Wisdom GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

FORA Wisdom GD40b/TD-4272B Blood Glucose Monitoring System

The FORA Wisdom GD40b / TD-4272B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates; nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40b / TD-4272B Test Strips are for use with the FORA Wisdom GD40b / TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

6. Comparison to Predicate Device

The U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b

Blood Glucose Monitoring Systems are substantially equivalent to the predicate device FORA G31 Blood Glucose Monitoring System (K094005).

7. Performance Studies

The laboratory and clinical studies for the system performance of U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b Blood Glucose Monitoring Systems demonstrated the meters and test strips works well as a system.

8. Conclusion

The U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b Blood Glucose Monitoring Systems demonstrate satisfactory performance and meet its intended use. The U-RIGHT TD-4279 A/B Blood Glucose Monitoring Systems and FORA GD40a/b Blood Glucose Monitoring Systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 27 2011

Taidoc Technology Corporation
c/o Teling Hsu
3f,5f, No.127 Wugong 2nd Rd,
Wugu Township, Taipei County, Taiwan 24888

Re: k101509

Trade Name: U-RIGHT TD-4279A Blood Glucose Monitoring System
U-RIGHT TD-4279B Blood Glucose Monitoring System
U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System
U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System
FORA GD40a/TD-4272a Blood Glucose Monitoring System
FORA GD40b/TD-4272b Blood Glucose Monitoring System
FORA Wisdom GD40a/TD-4272a Blood Glucose Monitoring System
FORA Wisdom GD40b/TD-4272b Blood Glucose Monitoring System

Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: May 31, 2011
Received: June 22, 2011

Dear Ms. Hsu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal-Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **U-RIGHT TD-4279A Blood Glucose Monitoring System**

Indications For Use:

The U-Right TD-4279A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279A Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The U-Right TD-4279 A Test Strips are for use with the U-Right TD-4279A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _√_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **U-RIGHT TD-4279B Blood Glucose Monitoring System**

Indications For Use:

The U-Right TD-4279B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279B Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The U-Right TD-4279B Test Strips are for use with the U-Right TD-4279B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Prescription Use _____	And/Or	Over the Counter Use _√__.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name:

Indications For Use: **FORA GD40a/TD-4272A Blood Glucose Monitoring System**

The FORA GD40a/TD-4272A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40a/TD-4272A Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The FORA GD40a/TD-4272A Test Strips are for use with the FORA GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _√_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **FORA GD40b/TD-4272B Blood Glucose Monitoring System**

Indications For Use:

The FORA GD40b/TD-4272B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40b/TD-4272B Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The FORA GD40b/TD-4272B Test Strips are for use with the FORA GD40b/TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Prescription Use _____	And/Or	Over the Counter Use _√_.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System**

Indications For Use:

The U-Right TD-4279A MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279A MULTI Test Strips are for use with the U-Right TD-4279A MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

Prescription Use __√____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _√__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System**

Indications For Use:

The U-Right TD-4279B MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279B MULTI Test Strips are for use with the U-Right TD-4279B MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

Prescription Use __√____	And/Or	Over the Counter Use _√__.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **FORA Wisdom GD40a/TD-4272A Blood Glucose Monitoring System**

Indications For Use:

The FORA Wisdom GD40a/TD-4272A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40a /TD-4272A Test Strips are for use with the FORA Wisdom GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

Prescription Use __√____	And/Or	Over the Counter Use _√__.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509

Indications for Use

510(k) Number (if known): **k101509**

Device Name: **FORA Wisdom GD40b/TD-4272B Blood Glucose Monitoring System**

Indications For Use:

The FORA Wisdom GD40b/TD-4272B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40b/TD-4272B Test Strips are for use with the FORA Wisdom GD40b/TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _√__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101509